

Attorney Docket No.: DEX0478US.NP
Inventors: Wolfert et al.
Serial No.: 10/552,084
Filing Date: December 1, 2006
Page 2

RECEIVED
CENTRAL FAX CENTER
JAN 31 2008

REMARKS

Claims 1-11, 16, 18-21, 24, 25 and 30-32 are pending in the instant application. These claims have been subjected to the following Restriction Requirement:

Group I, claims 30-32, drawn to a kit comprising assays;

Group II, claims 1-11, 16 and 18-21, drawn to a method for assessing risk; and

Group III, claims 24-25, drawn to a method for treating a subject.

The Examiner suggests that Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. Specifically, the Examiner suggests that claim 1 is drawn to a method comprising LpPLA2 and CRP and analyzing risk and that Packard (NEJM, 2000) meets the limitations of claim 1. Thus, the Examiner suggests that the technical feature is not a contribution over the prior art and the claims lack unity.

Further, the Examiner suggests that the claims are directed to more than one species of the generic invention and that these species lack unity of invention because they are not so linked as to form a single general inventive

Attorney Docket No.: **DEX0478US.NP**
Inventors: **Wolfert et al.**
Serial No.: **10/552,084**
Filing Date: **December 1, 2006**
Page 3

RECEIVED
CENTRAL FAX CENTER
JAN 31 2008

concept under PCT Rule 13.1. The species are suggested to be as follows:

for Group I, variable/s measured, for example Lp-PLA2 and LDL or LpPLA2 and CRP;

for Group II, variable/s measured, for example Lp-PLA2 and LDL or LpPLA2 and CRP; and patient disorder/patient population; and

for Group III, patient population, for example above normal CRP and Lp-PLA2 or above normal Lp-PLA2 and low to normal LDL; and therapeutic molecule, a specific class of molecule, for example statin, Lp-PLA2 inhibitor or cholesterol reuptake inhibitor and a specific molecule.

Applicants respectfully traverse the Restriction and species election requirements.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that Packard (NEJM, 2000) meets the limitations of claim 1. Packard shows variables such as Lp-PLA2 and CRP individually predict risk of coronary events (Figure 1) and evaluates the statistical independence relative to other variables (Tables 2, 3 and 5). The instant application shows that Lp-PLA2 and CRP in combination synergistically predict risk of coronary events better than individually, which is not taught in Packard. Claims of the instant application are drawn to using the combined risks of both Lipoprotein Associated Phospholipase A2 (Lp-PLA2) and

Attorney Docket No.: DEX0478US.NP
Inventors: Wolfert et al.
Serial No.: 10/552,084
Filing Date: December 1, 2006
Page 4

RECEIVED
CENTRAL FAX CENTER

JAN 31 2008

C-reactive protein (CRP) or Low Density Lipoprotein Cholesterol (LDL) to assess the risk of CVD in the patient. This is clearly a special technical feature that defines a contribution which each of the claims considered as a whole, makes over the prior art. Withdrawal of this Restriction Requirement for lack of unity is therefore respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect Group II, claims 1-11, 16 and 18-21, with traverse.

Further, with respect to the species election requirement, MPEP § 808.01 states that an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case, however, the generic claim is not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only three variables are measured and only nine patient disorders are recited. Accordingly, reconsideration of this species election requirement is respectfully requested.

In an earnest effort to be completely responsive, however Applicants elect Lp-PLA2 and CRP, with traverse, and hypertension, with traverse.

Attorney Docket No.: DEX0478US.NP
Inventors: Wolfert et al.
Serial No.: 10/552,084
Filing Date: December 1, 2006
Page 5

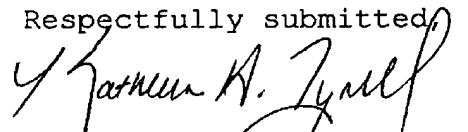
RECEIVED
CENTRAL FAX CENTER

JAN 31 2008

In accordance with MPEP § 809.01 and 37 C.F.R. § 1.146, it is respectfully pointed out that the claims should only be restricted to this species if no generic claim is held allowable.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,350

Date: January 31, 2008

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515